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In re application of:	Confirmation No.: 2843
ERIC E. KUO, et al.	Examiner: Not Yet Assigned
Application No.: 10/788,635	Technology Center/Art Unit: 3732
Filed: February 27, 2004	**RESPONSE TO NOTICE TO FILE CORRECTED APPLICATION PAPERS, PRELIMINARY AMENDMENT AND SUBMISSION OF FORMAL DRAWINGS AND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**
For: DENTAL DATA MINING	
Customer No.: 24710	

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Sir:

In response to the Notice to File Corrected Application Papers mailed 5/24/2004 attached are formal drawings for the above patent application. A copy of the Notice is returned with this reply.

Prior to examination of the application, Applicant hereby requests the following amendments be made to the specification and drawings. These amendments correct typographical errors. No new material has been added.

Amendments to the Specification begin on page 2 of this paper.

Amendments to the Drawings. As an appendix to this response, 6 sheets labeled "Annotated Sheet Showing Changes" are provided to show the changes to Figs. 1B, 1E, 1F, 2B, 4 and 7. Also attached are 14 sheets of formal drawings labeled "Replacement Sheet," which include the proposed changes. Applicants confirm that Fig. 11 is not part of the application and have cancelled the references to Fig. 11 in the following amendments to the specification. Withdrawal of the drawing rejections is hereby requested.

Amendments to the Specification:

Please make the following changes to the two paragraphs beginning at the third paragraph of page 2 through the first paragraph of page 3:

The achieved outcome, if measured, is usually determined using a set of standard criteria ~~(such as the American Board of Orthodontics)~~ such as by the American Board of Orthodontics, against which the final outcome is compared, ~~compared to,~~ and is usually a set of idealized norms of what the ideal occlusion and bite relationship ought to be. Another method of determining outcome is to use a relative improvement index such as PAR, IOTN, and ICON to measure degrees of improvement as a result of treatment.

The present invention provides methods and apparatus for mining relationships in treatment outcome and ~~usinge~~ using the mined data to enhance treatment plans or enhance appliance configurations in a process of repositioning teeth from an initial tooth arrangement to a final tooth arrangement. The invention can operate to define how repositioning is accomplished by a series of appliances or by a series of adjustments to appliances configured to reposition individual teeth incrementally. The invention can be applied advantageously to specify a series of appliances formed as polymeric shells having the tooth-receiving cavities, that is, shells of the kind described in U.S. Patent No. 5,975,893.~~the above-mentioned U.S. Application No. 09/169276, (Attorney Docket No. 018563-004800US-AT-00105US), filed Oct. 8, 1998.~~

Please make the following changes to the paragraph beginning at page 4 and ending at page 5:

In general, in one aspect, the invention provides methods and corresponding apparatus for segmenting an orthodontic treatment path into clinically appropriate

substeps for repositioning the teeth of a patient. The methods include providing a digital finite element model of the shape and material of each of a sequence of appliances to be applied to a patient; providing a digital finite element model of the teeth and related mouth tissue of the patient; computing the actual effect of the appliances on the teeth by analyzing the finite elements models computationally; and evaluating the effect against clinical constraints. Advantageous implementations can include one or more of the following features. The appliances can be braces, including brackets and archwires, polymeric shells, including shells manufactured by stereo lithography, retainers, or other forms of orthodontic appliance. Implementations can include comparing the actual effect of the appliances with an intended effect of the appliances; and identifying an appliance as an unsatisfactory appliance if the actual effect of the appliance is more than a threshold different from the intended effect of the appliance and modifying a model of the unsatisfactory appliance according to the results of the comparison. The model and resulting appliance can be modified by ~~modifying~~ altering the shape of the unsatisfactory appliance, by adding a dimple, by adding material to cause an overcorrection of tooth position, by adding a ridge of material to increase stiffness, by adding a rim of material along a gumline to increase stiffness, by removing material to reduce stiffness, or by redefining the shape to be a shape defined by the complement of the difference between the intended effect and the actual effect of the unsatisfactory appliance. The clinical constraints can include a maximum rate of displacement of a tooth, a maximum force on a tooth, and a desired end position of a tooth. The maximum force can be a linear force or a torsional force. The maximum rate of displacement can be a linear or an angular rate of displacement. The apparatus of the invention can be implemented as a system, or it can

be implemented as a computer program product, tangibly stored on a computer-readable medium, having instructions operable to cause a computer to perform the steps of the method of the invention.

At page 7, please make the following changes to paragraphs 16-19:

FIG. 8 ~~are~~ shows exemplary diagrams of root modeling.

FIG. 9 ~~are~~ shows exemplary diagrams of CT scan of teeth.

FIG. 10 shows an exemplary user interface showing teeth.

~~FIG. 11 shows the exemplary diagram of FIG. 10 with root data.~~

Please make the following changes to the four paragraphs beginning at the first paragraph of page 8 through the first paragraph of page 9:

~~F Digital~~ Digital treatment plans are now possible with 3-dimensional orthodontic treatment planning tools such as ClinCheck® from Align Technology, Inc. or other software available from eModels and OrthoCAD, among others. These technologies allow the clinician to use the actual patient's dentition as a starting point for customizing the treatment plan. The ClinCheck® technology uses a patient-specific digital model to plot a treatment plan, and then use a scan of the achieved treatment outcome to assess the degree of success of the outcome as compared to the original digital treatment plan as discussed in U.S. Patent Application Serial No. 10/640,439, filed August 21, 2003 and U.S. Patent Application Serial No. 10/225,889 filed August 22, 2002. ~~(previously filed patent for this technology – superimposition tool.~~ The problem with the digital treatment plan and outcome assessment is the abundance of data and the lack of standards and

efficient methodology by which to assess "treatment success" at ~~a individual~~ an individual patient level. To analyze the information, a dental data mining system is used.

FIG. 1A shows one exemplary dental data mining system. In this system, dental treatment and outcome data sets 1 are stored in a database or information warehouse 2. The data is extracted by data ~~by a data~~ mining software 3 that generates results 4. The data mining software can interrogate the information captured and/or updated in the database 2 and can generate an output data stream correlating a patient tooth problem with a dental appliance solution. Note that the output of the data mining software can be most advantageously, self-reflexively, fed as a subsequent input to at least the database and the data mining correlation algorithm.

The result of the data mining system of ~~FIG. 1~~ FIG. 1A is used for defining appliance configurations or changes to appliance configurations for incrementally moving teeth. The tooth movements will be those normally associated with orthodontic treatment, including translation in all three orthogonal directions, ~~relative to a vertical centerline,~~ rotation of the tooth centerline in the two orthogonal ~~orthodontic~~ directions with rotational axes perpendicular to a vertical centerline ("root angulation" and "torque"), as well as rotation of the tooth centerline ~~about~~ in the orthodontic direction with an axis parallel to the vertical centerline ~~the centerline~~ ("pure rotation").

In one embodiment, the data mining system captures the 3-D treatment planned movement, ~~plan,~~ the start position and the final achieved dental position. The system compares the outcome to the plan, and the outcome can be achieved using any treatment methodology including removable appliances as well as fixed appliances such as orthodontic brackets and wires, or even other dental treatment such as comparing

achieved to plan for orthognathic surgery ~~(may be patents out there because there exists software that compares outcome facial profile to predictive 2-D images)~~, periodontics, restorative, among others.

Please make the following changes to the third paragraph of page 9, ending at page 10:

FIG. 1B shows an analysis of the performance of one or more dental appliances. "Achieved" movement is plotted against "Goal" movement in scatter graphs, and trend lines are generated. Scatter graphs are shown to demonstrate where all "scattered" data points are, and trend lines are generated to show the performance of the dental appliances. In one embodiment, trend lines are selected to be linear (they can be curvilinear); thus trend lines present as the "best fit" straight lines for all "scattered" data. The performance of the Aligners is represented as the slope of a trend line. The Y axis intercept ~~is~~ models the incidental movement that occurs when wearing the Aligners. Predictability is measured ~~by R2~~ by R^2 that is obtained from a regression computation of "Achieved" and ~~"Goal."~~ "Goal" data. ~~A number of scatter graphs are shown below.~~

Please make the following changes to the second paragraph of page 10:

FIG. 1D shows an analysis of the performance of one or more dental appliances. For the type of motion illustrated by FIG. 1D, the motion achieved is about 85% of targeted motion ~~shows that Incisor Intrusions are well controlled, that is, the target goal is achieved about 85% of the time~~ for that particular set of data.

Please make the following changes to the two paragraphs starting at the bottom of page 10 through the first paragraph of page 11:

In one embodiment, clinical parameters in steps such as 170 (FIG. 2A) and 232 (FIG. 2B) are made more precise ~~and safer~~ by allowing for the statistical deviation of targeted from actual tooth position. For example, a subsequent movement target might be reduced because of a large calculated probability of currently targeted tooth movement not having been achieved adequately, with the result that there is a high probability the subsequent movement stage will need to complete work intended for an earlier stage. Similarly, targeted movement might overshoot desired positions especially in earlier stages so that expected actual movement is better controlled. This embodiment sacrifices the goal of minimizing round trip time in favor of achieving a higher probability of targeted end-stage outcome. This methodology is accomplished within treatment plans specific to clusters of similar patient cases.

Table 1 shows grouping of teeth in one embodiment. The sign convention of tooth movements is indicated in Table 2. Different tooth movements of the selected 60 arches were demonstrated in Table 3 with performance sorted by descending order. The appliance performance can be broken into 4 separate groups: high (79-85%), average (60-68%), below average (52-55%), and inadequate (24-47%). Table 4 shows ranking of movement predictability. Predictability is broken into 3 groups: highly predictable (.76-.82), predictable (.43-.63) and unpredictable (.10-.30). For the particular set of data, for example, the findings are as follows:

Please make the following changes paragraphs number 3 and 4 of page 12:

3. Bicuspid tipping, bicuspid mesialization, molar rotation, and posterior expansion performance are below average. The range for bicuspid mesialization is about 1 millimeter, for bicuspid tipping is about 19 degrees, for molar rotation is about 27 degrees and for posterior expansion is about 2.8 millimeters. Bicuspid tipping and mesialization are unpredictable, whereas ~~. Whereas~~ the rest are predictable movements.

4. Anterior and incisor extrusion, round teeth and bicuspid rotation, canine tipping, molar distalization, posterior torque performance are inadequate. The range of anterior extrusion is about 1.7 millimeters, for incisor extrusion is about 1.5mm, for round teeth rotation is about 67 degrees for bicuspid rotation is about 63 degrees, for canine tipping is about 26 degrees, for molar distalization is about 2 millimeters, and for posterior torque is about 43 degrees. All are unpredictable ~~movement~~ movements except bicuspid rotation which is predictable.

Please make the following change to the bottom of the table at page 14:

Group	Movement	Model	Performance Index	Side Effect	Predictability
Incisor	Intrusion	Linear	85%	0.03	0.82
Anterior	Intrusion	Linear	79%	0.03	0.76
Canine	Intrusion	Linear	68%	-0.10	0.43
Incisor	Torque	Linear	67%	0.21	0.63
Anterior	Torque	Linear	62%	0.15	0.56
Incisor	Rotation	Linear	61%	-0.09	0.76
Bicuspid	Tipping	Linear	55%	0.35	0.27
Molar	Rotation	Linear	52%	0.11	0.58
Posterior	Expansion	Linear	52%	0.11	0.48
Bicuspid	Mesialization	Linear	52%	0.00	0.30
Bicuspid	Rotation	Linear	47%	0.28	0.63

Molar	Distalization	Linear	43%	0.02	0.20
Canine	Tipping	Linear	42%	0.10	0.28
Posterior	Torque	Linear	42%	1.50	0.28
Round	Rotation	Linear	39%	-0.14	0.27
Anterior	Extrusion	Linear	29%	-0.02	0.13
Incisor	Extrusion	Linear	24%	0.02	0.10

~~Table 4~~ Table 3. Ranking of Performance Index of movement

Please make the following changes to the first and second paragraphs of page 17:

In one embodiment, the data mining software 3 (FIG. 1A) can be a "spider" or "crawler" to grab data on the database 2 (FIG. 1A) for indexing. In one embodiment, clustering operations are performed to detect patterns in the data. In another embodiment, a neural network is used to recognize each pattern as the neural network is quite robust at recognizing dental treatment patterns. Once the treatment features have been characterized, the neural network then compares the input dental information with stored templates of treatment vocabulary known by the neural network recognizer, among others. The recognition models can include a Hidden Markov Model (HMM), a dynamic programming model, a neural network, a fuzzy logic, or a template matcher, among others. These models may be used singly or in combination.

Dynamic programming considers all possible ~~points~~ paths of M "frames" through N points, subject to specified costs for making transitions from any point i at any given frame k to any point j at the next frame k+1. ~~within the permitted domain for each value of i.~~ Because the best path from the current point to the next point is independent of what happens beyond that point, ~~point. Thus,~~ the minimum total cost ~~cost of~~ [i(k), j(k+1)] of a path through i(k) ending at j(k+1) is the cost of the transition itself plus the cost of the minimum path to i(k). ~~it.~~ Preferably, the values of the predecessor paths ~~predecessors~~ can

be kept in an MxN array, and the accumulated cost kept in a 2xN array to contain the accumulated costs of the possible immediately preceding column and the current column. However, this method requires significant computing resources.

Please make the following changes to the five paragraphs beginning at the second paragraph of page 18 through the 1st paragraph of page 20:

In the preferred embodiment, the Markov ~~network~~ model is used to model probabilities for sequences of ~~a number of dental~~ treatment ~~options~~observations. The transitions between states are represented by a transition matrix A = [a(i,j)]. Each a(i,j) term of the transition matrix is the probability of making a transition to state j given that the model is in state i. The output symbol probability of the model is represented by a set of functions B=[b(j), ~~B=[b(j) (O(t)],~~ where the b(j) ~~b(j) (O(t)~~ term of the output symbol matrix is the function that when evaluated on an specified value O(t) returns the probability of outputting observation O(t), given that the model is in state j. The first state is always constrained to be the initial state for the first time frame of the ~~utterance~~Markov chain, ~~as~~ only a prescribed set of left to right state transitions are possible. A predetermined final state is defined from which transitions to other states cannot occur.

In one embodiment, transitions ~~Transitions~~ are restricted to reentry of a state or entry to one of the next two states. Such transitions are defined in the model as transition probabilities. For example, a treatment pattern currently having a frame of feature signals in state 2 has a probability of reentering state 2 of a(2,2), a probability a(2,3) of entering state 3 and a probability of a(2,4) =1 - a(2,2) - a(2,3) ~~a(2,4) =1 - a(2,1) - a(2,2)~~

of entering state 4. The probability a(2,1) of entering state 1 or the probability a(2,5) of entering state 5 is zero and the sum of the probabilities a(2,1) through a(2,5) is one. Although the preferred embodiment restricts the flow graphs to the present state or to the next two states, one skilled in the art can build an HMM model ~~without any~~with more flexible transition restrictions, although the sum of all the probabilities of transitioning from any state must still add up to one.

In each state j ~~state~~ of the model, the current feature frame may be identified with one of a set of predefined output symbols or may be labeled probabilistically. In this case, the output symbol probability b(j) (O(t)) ~~b(j) O(t)~~ corresponds to the probability assigned by the model that the feature frame symbol is O(t). The model arrangement is a matrix A=[a(i,j)] of transition probabilities and a technique of computing B=[b(j) (O(t))]. ~~B=b(j) O(t), the feature frame symbol probability in state j~~.

In one embodiment, the ~~The~~ Markov model is formed for a reference pattern from a plurality of sequences of training patterns and the output symbol probabilities are multivariate Gaussian function probability densities. The dental treatment information traverses through the feature extractor. During learning, the resulting feature vector series is processed by a parameter estimator, whose output is provided to the hidden Markov model. The hidden Markov model is used to derive a set of reference pattern templates, each template representative of an identified pattern in a vocabulary set of reference treatment patterns. The Markov model reference templates are next utilized to classify a sequence of observations into one of the reference patterns based on the probability of generating the observations from each Markov model reference pattern

template. During recognition, the unknown pattern can then be identified as the reference pattern with the highest probability in the likelihood calculator.

The HMM template has a number of states, each having a discrete value. However, ~~because~~ treatment pattern features may have a dynamic pattern in contrast to a single value, the ~~value. The~~ addition of a neural network at the front end of the HMM in an embodiment provides the capability of representing states with dynamic values. The input layer of the neural network comprises input neurons. The outputs of the input layer are distributed to all neurons in the middle layer. Similarly, the outputs of the middle layer are distributed to all output ~~states~~ neurons, which output neurons correspond one-to-one with internal states of the HMM.~~normally would be the output layer of the neuron~~. However, each output has transition probabilities to itself or to other ~~the next~~ outputs, thus forming a modified HMM. Each state of the thus formed HMM is capable of responding to a particular dynamic signal, resulting in a more robust HMM. Alternatively, the neural network can be used alone without resorting to the transition probabilities of the HMM architecture.

Please make the following changes to the paragraph at the bottom of page 21 ending at page 22:

Data mining can discover statistically significant patterns of different treatment ~~outcome~~ outcomes achieved by different clinicians for comparable patients. For example, patient cases clustered together might have systematically fewer complications with one clinician as compared to another. Such a difference detected by the data mining tool

might be used as a flag for feedback to the more poorly performing clinician as well as a flag for solicitation of treatment differences used by the better performing clinician.

Please make the following changes to the two paragraphs beginning at the bottom of page 22 through the first paragraph of page 23:

FIG. 1E shows an exemplary process for clusterizing practices. First, the process clusterizes treatment practice based on clinician treatment history such as treatment preferences, outcomes, and demographic and practice ~~& practice~~ variables (20). Next, the system models preferred clinical constraints within each cluster (22). Next, the system assigns clinicians without treatment history to clusters in 20 based on demographic and practice variables (24). In one embodiment, the system performs process 100 (see FIG. 2A) separately within each cluster, using cluster-specific clinical constraints (26). Additionally, the system updates ~~update~~ clusters and cluster assignments ~~assignment~~ as new treatment and outcome data arrives (28).~~outcomes data arrive (28).~~

Fig. 1F shows another embodiment of a data mining system to generate proposed treatments. First, the system identifies/clusterizes patient histories having detailed follow-up (such as multiple high-resolution scans), based on detailed follow-up data, diagnosis, treatment parameters and outcomes, and demographic variables (40). Within each cluster, the system models discrepancies between intended position and actual positions obtained from follow-up data (42). Further, within each cluster, the system models risk for special undesirable outcomes (44). At a second tier of clustering, patient ~~patient~~ histories with less detailed follow-up data are clusterized ~~with less detailed follow-up data~~ based on available variables. The second-tier clustering is partial enough

that each of the larger number of second tier ~~Assign to~~ clusters can either be assigned to clusters calculated in 40 or else considered a new cluster (46). The system refines step 42 models with additional records from step 46 clusters (48). It can also refine step 44 models with additional records from step 48 clusters (50). At a third tier of clustering, the ~~the~~ system then assigns new patients to step 46 clusters based on diagnosis, demographic, and initial physical (52). Within each step 52 cluster, the system models expected discrepancies between intended position and actual positions (54). From step 54, the system uses revised expected position information where relevant (including ~~232, 250)~~ 232 and 250, FIG. 2B) (67). Additionally, within each step 52 cluster, the system models risk for undesirable outcomes (56). From step 56, the system also flags cases that require special attention and clinical constraints (as in 204 and 160, FIGS. 2B and 2A) ~~204, 160)~~ (69). The process then customizes treatment plan to each step 52 cluster (58). Next, the system iteratively collects data (61) and loops back to (40). Additionally, clusters can be revised and reassigned (63). The system also continually identifies clusters without good representation ~~in step 40 clusters~~ for additional follow-up analysis (65).

Please make the following changes to the first and second paragraphs of page 24:

Due to these and other ~~limitation,~~ limitations, treatment planning is necessarily made based on partial information.

In one embodiment, ~~such missing~~ missing information is approximated substantially by matching predictive characteristics between patients and a representative sample for which detailed follow-up information is collected. In this case, patients are

flagged based on poorly anticipated treatment outcomes for requests for follow-up information, such as collection and analysis of additional sets of tooth impressions. Resulting information is then used to refine patient clusters and treatment of patients later assigned to the clusters.

Please make the following changes to the first paragraph of page 25:

As an initial step, a mold or a scan of patient's teeth or mouth tissue is acquired (110). This step generally involves taking casts of the patient's teeth and gums, and may ~~also~~ in addition or alternately involve taking wax bites, direct contact scanning, x-ray imaging, tomographic imaging, sonographic imaging, and other techniques for obtaining information about the position and structure of the teeth, jaws, gums and other orthodontically relevant tissue. From the data so obtained, a digital data set is derived that represents the initial (that is, pretreatment) arrangement of the patient's teeth and other tissues.

Please make the following changes to the first paragraph of page 26:

Having both a beginning position and a final position for each tooth, the process next defines a tooth path for the motion of each tooth. In one embodiment, the ~~The~~ tooth paths are optimized in the aggregate so that the teeth are moved in the quickest fashion with the least amount of round-tripping to bring the teeth from their initial positions to their desired final positions. (Round-tripping is any motion of a tooth in any direction other than directly toward the desired final position. Round-tripping is sometimes necessary to allow teeth to move past each other.) The tooth paths are segmented. The

segments are calculated so that each tooth's motion within a segment stays within threshold limits of linear and rotational translation. In this way, the end points of each path segment can constitute a clinically viable repositioning, and the aggregate of segment end points constitute a clinically viable sequence of tooth positions, so that moving from one point to the next in the sequence does not result in a collision of teeth.

Please make the following changes to the first paragraph of page 28, ending at page 29:

FIG. 2B illustrates a process 200 implementing the appliance-calculation step (FIG. 2A, step 170) for polymeric shell aligners of the kind described in above-mentioned ~~patent application no. 09/169,276 (attorney docket no. 018563-004800).~~ U.S. Patent No. 5,975,893. Inputs to the process include an initial aligner shape 202, various control parameters 204, and a desired end configuration for the teeth at the end of the current treatment path segment 206. Other inputs include digital models of the teeth in position in the jaw, models of the jaw tissue, and specifications of an initial aligner shape and of the aligner material. Using the input data, the process creates a finite element model of the aligner, teeth and tissue, with the aligner in place on the teeth (step 210). Next, the process applies a finite element analysis to the composite finite element model of aligner, teeth and tissue (step 220). The analysis runs until an exit condition is reached, at which time the process evaluates whether the teeth have reached the desired end position for the current path segment, or a position sufficiently close to the desired end position (step 230). If an acceptable end position is not reached by the teeth, the process calculates a new candidate aligner shape (step 240). If an acceptable end position is

reached, the motions of the teeth calculated by the finite elements analysis are evaluated to determine whether they are orthodontically acceptable (step 232). If they are not, the process also proceeds to calculate a new candidate aligner shape (step 240). If the motions are orthodontically acceptable and the teeth have reached an acceptable position, the current aligner shape is compared to the previously calculated aligner shapes. If the current shape is the best solution so far (decision step 250), it is saved as the best candidate so far (step 260). If not, it is saved in an optional step as a possible intermediate result (step 252). If the current aligner shape is the best candidate so far, the process determines whether it is good enough to be accepted (decision step 270). If it is, the process exits. Otherwise, the process continues and calculates another candidate shape (step 240) for analysis.

Please make the following changes to the first and second paragraphs of page 31:

FIG. 4 shows a process 400 for calculating the shape of a next aligner that can be used in the aligner calculations, step 240 of process 200 (FIG. 2B). ~~(FIG. 2).~~ A variety of inputs are used to calculate the next candidate aligner shape. These include inputs 402 of data generated by the finite element analysis solution of the composite model and data 404 defined by the current tooth path. The data 402 derived from the finite element analysis includes the amount of real elapsed time over which the simulated repositioning of the teeth took place; the actual end tooth positions calculated by the analysis; the maximum linear and torsional force applied to each tooth; the maximum linear and angular velocity of each tooth. From the input path information, the input data 404 includes the initial tooth positions for the current path segment, the desired tooth

positions at the end of the current path segment, the maximum allowable displacement velocity for each tooth, and the maximum allowable force of each kind for each tooth.

If a previously evaluated aligner was found to violate one or more constraints, additional input data 406 can optionally be used by the process 400. This data 406 can include information identifying the constraints violated by, and any identified suboptimal performance of, the previously evaluated aligner. Additionally, input data 408 relating to constraints violated by, and suboptimal performance of previous dental devices can be used by the process 400.

Please make the following changes to the two paragraphs on page 33 ending at page 34:

Rules 452a...452n ~~452~~ have the conventional two-part form: an if-part defining a condition and a then-part defining a conclusion or action that is asserted if the condition is satisfied. Conditions can be simple or they can be complex conjunctions or disjunctions of multiple assertions. An exemplary set of rules, which defines changes to be made to the aligner, includes the following: if the motion of the tooth is too ~~slow,~~ fast, add driving material to the aligner opposite the desired direction of motion; if the motion of the tooth is too slow, add driving material to overcorrect the position of the tooth; if the tooth is too far short of the desired end position, add material to overcorrect; if the tooth has been moved too far past the desired end position, add material to stiffen the aligner where the tooth moves to meet it; if a maximum amount of driving material has been added, add material to overcorrect the repositioning of the tooth and do not add driving material; if

the motion of the tooth is in a direction other than the desired direction, remove and add material so as to redirect the tooth.

In an alternative embodiment, illustrated in FIGS. 5B and 5C, an absolute configuration of the aligner is computed, rather than an incremental difference. As shown in FIG. 5B, a process 460 computes an absolute configuration for an aligner in a region of a current tooth. Using input data that has already been described, the process computes the difference between the desired end position and the achieved end position of the current tooth (462). Using the intersection of the tooth center line with the level of the gum tissue as the point of reference, the process computes the complement of the difference in all six degrees of freedom of motion, namely three degrees of translation and three degrees of rotation (step 464). Next, the model tooth is displaced from its desired end position by the amounts of the complement differences (step 466), which is illustrated in FIG. 5B. ~~FIG. 5D.~~

Please make the following changes to the eight paragraphs beginning at the third paragraph of page 34 through the third paragraph of page 37:

As shown in FIG. 6, the process 200 (FIG. 2B) of computing the shape for an aligner for a step in a treatment path is one step in ~~an overall~~ a process 600 of computing the shapes of a series of aligners. This ~~overall~~ process 600 begins with an initialization step 602 in which initial data, control and constraint values are obtained.

When an aligner configuration has been found for each step or segment of the treatment path (step 604), the ~~overall~~ process 600 determines whether all of the aligners are acceptable (step 606). If they are, the process ~~exits and~~ is complete. Otherwise, the

process optionally undertakes a set of steps 610 in an attempt to calculate a set of acceptable aligners. First, one or more of the constraints on the aligners is relaxed (step 612). Then, for each path segment with an unacceptable aligner, the process 200 (FIG. 2B) of shaping an aligner is performed with the new constraints (step 614). If all the aligners are now acceptable, the ~~overall~~ process 600 exits (step 616).

Aligners may be unacceptable for a variety of reasons, some of which are handled by the ~~overall~~ process. For example, if any impossible movements were required (decision step 620), that is, if the shape calculation process 200 (FIG. 2B) was required to effect a motion for which no rule or adjustment was available, the process 600 proceeds to execute a module that calculates the configuration of a hardware attachment to the subject tooth to which forces can be applied to effect the required motion (step 640). Because adding hardware can have an effect that is more than local, when hardware is added to the model, the outer loop of the ~~overall~~ process 600 is executed again (step 642).

If no impossible movements were required ("no" branch from step 620), the process transfers control to a path definition process (such as step 150, FIG. 2A) to redefine those parts of the treatment path having unacceptable aligners (step 630). This step can include both changing the increments of tooth motion, i.e., changing the segmentation, on the treatment path, changing the path followed by one or more teeth in the treatment path, or both. After the treatment path has been redefined, the outer loop of the ~~overall~~ process is executed again (step 632). The recalculation is advantageously limited to recalculating only those aligners on the redefined portions of the treatment path. If all the aligners are now acceptable, the ~~overall~~ process exits (step 634). If unacceptable aligners still remain, the ~~overall~~ process can be repeated until an acceptable

set of aligners is found or an iteration limit is exceeded (step 650). At this point, as well as at other points ~~point~~ in the processes that are described in this specification, such as at the computation of additional hardware (step 640), the process can interact with a human operator, such as a clinician or technician, to request assistance (step 652). Assistance that an operator provides can include defining or selecting suitable attachments to be attached to a tooth or a bone, defining an added elastic element to provide a needed force for one or more segments of the treatment path, suggesting an alteration to the treatment path, either in the motion path of a tooth or in the segmentation of the treatment path, and approving a deviation from or relaxation of an operative constraint.

As was mentioned above, the ~~overall~~ process 600 is defined and parameterized by various items of input data (step 602). In one implementation, this initializing and defining data includes the following items: an iteration limit for the outer loop of the overall process; specification of figures of merit that are calculated to determine whether an aligner is good enough (see FIG. 2B, ~~FIG. 2,~~ step 270); a specification of the aligner material; a specification of the constraints that the shape or configuration of an aligner must satisfy to be acceptable; a specification of the forces and positioning motions and velocities that are orthodontically acceptable; an initial treatment path, which includes the motion path for each tooth and a segmentation of the treatment path into segments, each segment to be accomplished by one aligner; a specification of the shapes and positions of any anchors installed on the teeth or otherwise; and a specification of a model for the jaw bone and other tissues in or on which the teeth are situated (in the implementation being described, this model consists of a model of a viscous substrate fluid in which the teeth

are embedded and which has boundary conditions that essentially define a container for the fluid).

FIG. 7 is an exemplary diagram of a statistical root model. As shown therein, using the scanning processes described above, a scanned upper portion 701 ~~portion 700~~ of a tooth is identified. The scanned upper portion, including the crown, is then supplemented with a modeled 3D root. The 3D model of the root can be statistically modeled. The 3D model of the root 702 and the 3D model of the upper portion 700 together form a complete 3D model of a tooth.

FIG. 8 ~~are~~ shows exemplary diagrams of root modeling, as enhanced using additional dental information. In FIG. 8, the additional dental information is X-ray information. An X-ray image 710 of teeth is scanned to provide a 2D view of the complete tooth shapes. An outline of a target tooth is identified in the X-Ray image. The model 712 as developed in FIG. 7 is modified in accordance with the additional information. In one embodiment, the tooth model of FIG. 7 is morphed to form a new model 714 that conforms with the X-ray data.

FIG. 9 ~~are~~ shows an exemplary diagram ~~diagrams~~ of a CT scan of teeth. In this embodiment, the roots are derived directly from a high-resolution CBCT scan of the patient. Scanned roots can then be applied to crowns derived from an impression, or used with the existing crowns extracted from Cone Beam Computed Tomography (CBCT) data. A CBCT single scan gives 3D data and multiple forms of X-ray-like data. PVS impressions are avoided.

Please make the following changes to the first paragraph of page 38:

FIG. 10 shows an exemplary user interface showing the erupted teeth, which can be shown with root information in another embodiment. ~~while FIG. 11 shows the exemplary diagram of the teeth of FIG. 10 with root information~~. Each tooth is individually adjustable using a suitable handle. In the embodiment of ~~FIG. 10 and 11,~~ FIG. 10, the handle allows an operator to move the tooth in three-dimensions with six degrees of freedom.

Please change the title of page 47 as follows:

~~SUMMARY~~ABSTRACT

Systems and methods are disclosed providing a database comprising a compendium of at least one of patient treatment history; orthodontic therapies, orthodontic information and diagnostics; employing a data mining technique for interrogating said database for generating an output data stream, the output data stream correlating a patient malocclusion with an orthodontic treatment; and applying the output data stream to improve a dental appliance or a dental appliance usage.

REMARKS

The proposed amendments correct errors in the specification and drawings. No new material has been added. Entry of these amendments is respectively requested.

Applicants confirm that Fig. 11 is not part of the present application. In this response Applicant has cancelled the references in the specification to Fig. 11. As an appendix to this amendment, three sheets labeled "Annotated Sheet Showing Changes" are provided to show the changes to Fig. 1E, Fig. 2B and Fig. 4. Also attached are 14 sheets of formal drawings labeled "Replacement Sheet," which include the proposed changes.

Filed herewith is a supplemental Information Disclosure Statement for consideration by the Examiner in the present application.

Please charge any fees or credit overpayment to Deposit Account No. 50-1399.

Respectfully submitted,

Bao Q. Tran
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Dated: July 26, 2004

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ALIGN TECHNOLOGY, INC.

By: Clare C. Finney
Clare C. Finney

On July 26, 2004

Serial No. 10/788,635 Filed 2/27/2004
Inventors: Eric E. Kuo, et al.
Docket No. AT-000224
ANNOTATED SHEET SHOWING CHANGES

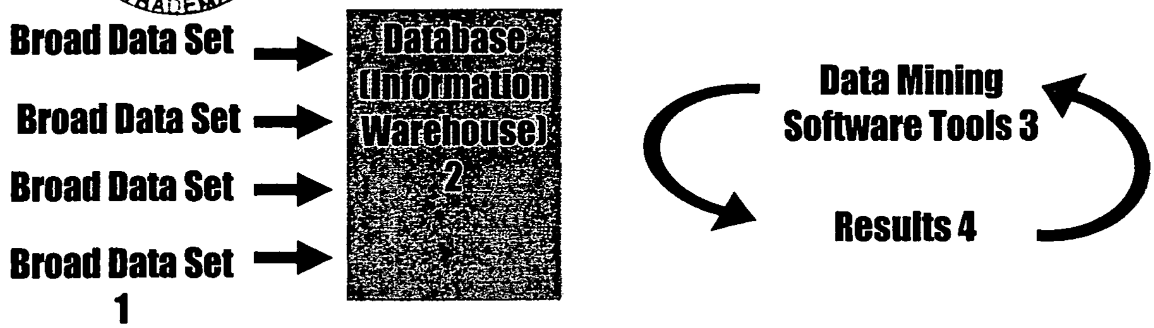
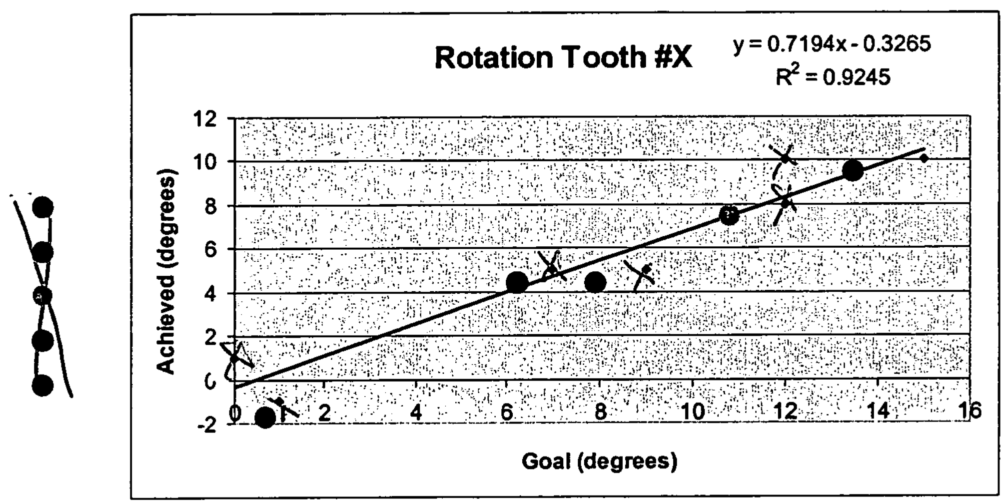


FIG. 1A



Slope = Performance Index
R^2 = Predictability

FIG. 1B

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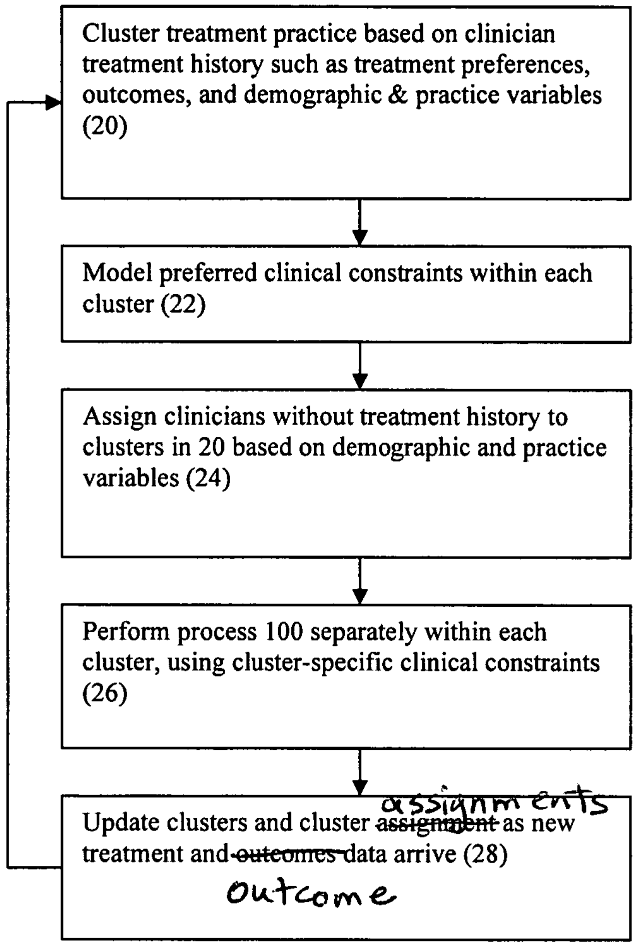

FIG. 1E

Serial No. 10/788,635 Filed 2/27/2004
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Docket No. AT-000224
ANNOTATED SHEET SHOWING CHANGES

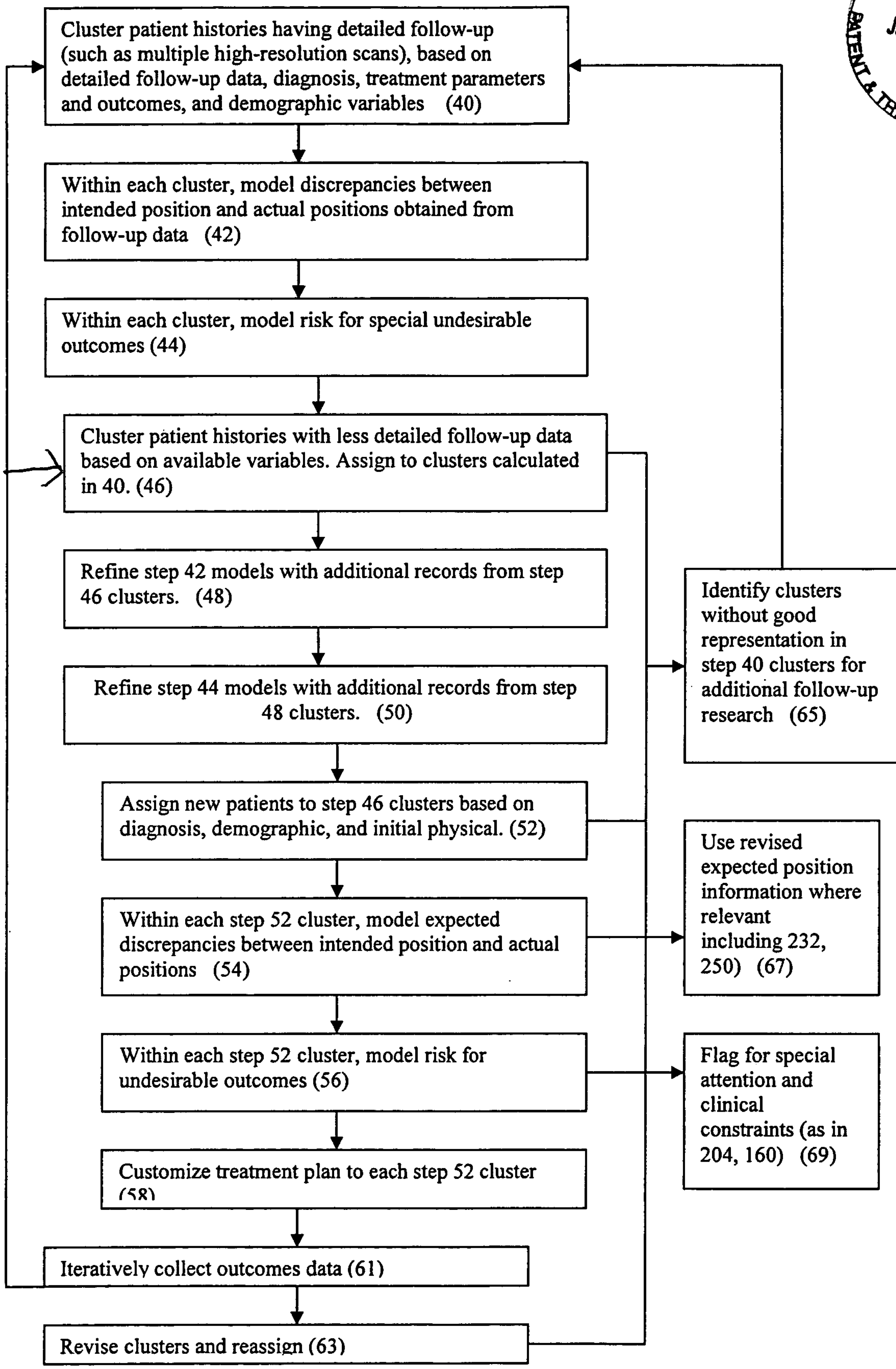

FIG. 1F

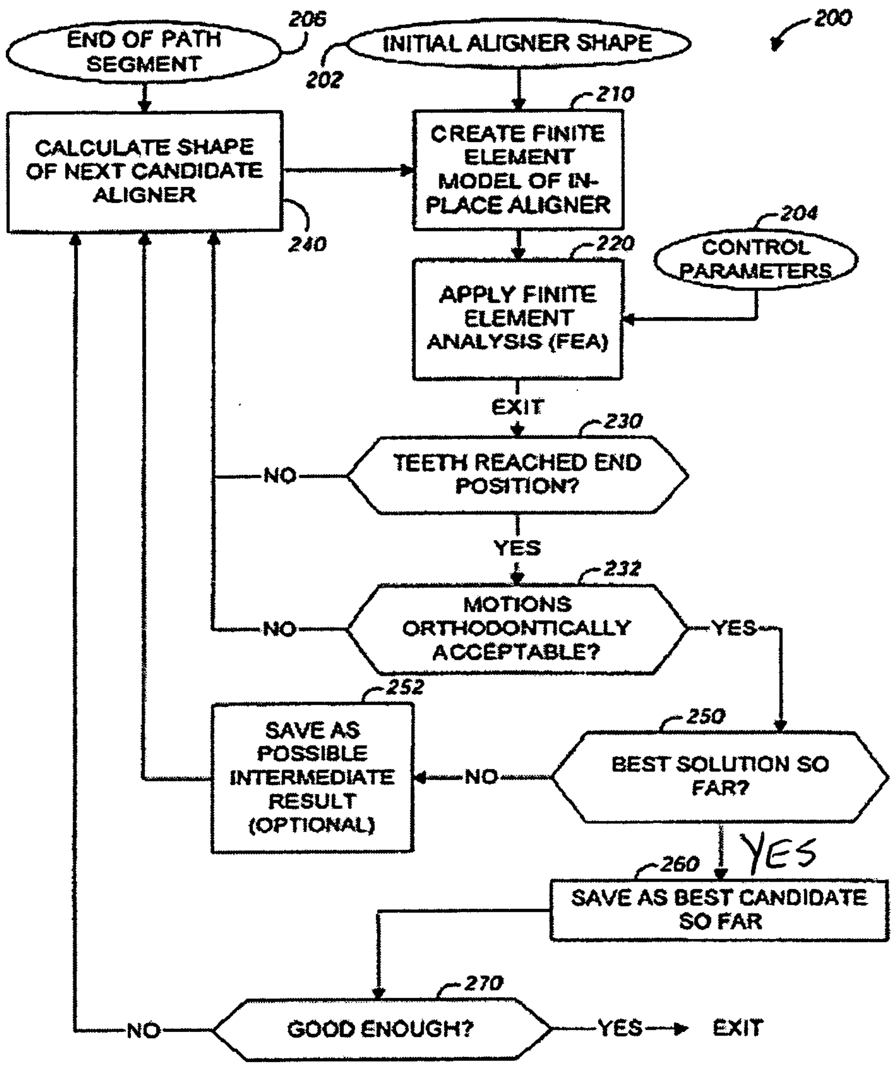
200
206
END OF PATH SEGMENT
202
INITIAL ALIGNER SHAPE
210
CALCULATE SHAPE OF NEXT CANDIDATE ALIGNER
240
CREATE FINITE ELEMENT MODEL OF IN-PLACE ALIGNER
204
CONTROL PARAMETERS
220
APPLY FINITE ELEMENT ANALYSIS (FEA)
EXIT
230
TEETH REACHED END POSITION?
NO
YES
232
MOTIONS ORTHODONTICALLY ACCEPTABLE?
NO
YES
252
SAVE AS POSSIBLE INTERMEDIATE RESULT (OPTIONAL)
NO
250
BEST SOLUTION SO FAR?
YES
260
SAVE AS BEST CANDIDATE SO FAR
270
GOOD ENOUGH?
NO
YES
EXIT

FIG. 2B

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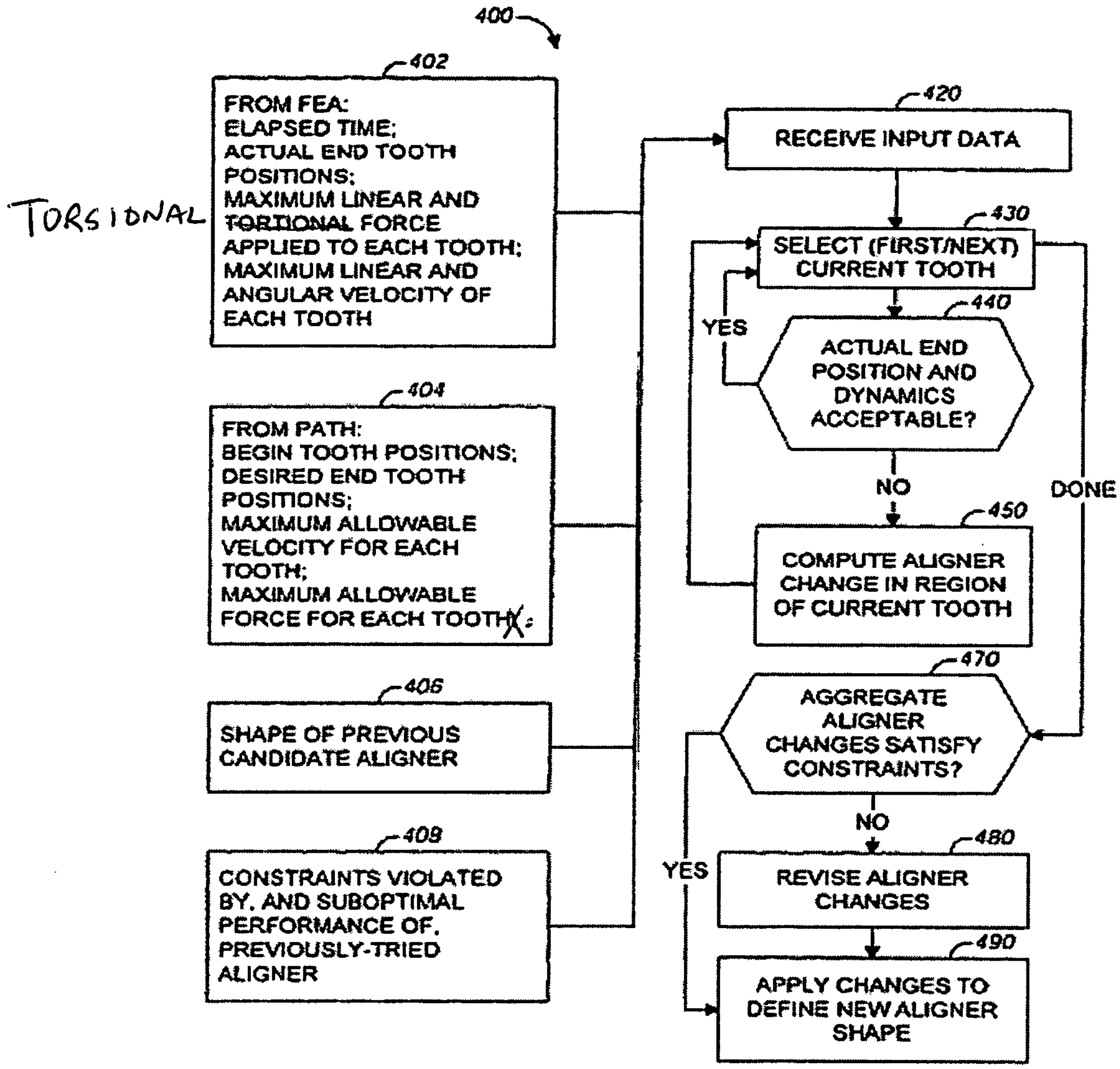

FIG. 4

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ANNOTATED SHEET SHOWING CHANGES

FIG. 7